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February 18, 2009

VIA HAND DELIVERY

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Re: FDA-2009-P-0038

Dear Sir or Madam:

On behalf of Actavis Elizabeth LLC, we are submitting this response to the January 29, 2009 citizen petition filed by Mayne Pharma International Pty. Ltd., Warner Chilcott (US), LLC, Warner Chilcott Laboratories Ireland Ltd. and Warner Chilcott Company, Inc. (collectively "Warner Chilcott"). This petition borders on the frivolous, should not cause any delay in the review and/or approval of any pending ANDAs and should be immediately rejected.

Ignoring well-established law to the contrary, Warner Chilcott would have FDA stay approval of certain ANDAs seeking approval of a generic version of Warner Chilcott's Doryx® product (doxycycline hyclate) for 30 months even though these ANDAs were on file before Warner-Chilcott listed any patent in the Orange Book. Warner Chilcott argues that Congress' application of the Hatch-Waxman Act to "old antibiotics" in the QI Program Supplemental Funding Act of 2008, Pub. L. No. 110-379, 122 Stat. 4075, 4077-4078 (2008) (the "QI Act") should be interpreted – without any congressional, judicial, scholarly or policy support whatsoever – to mean that Congress actually intended to apply only the Hatch-Waxman Act as it existed in 1984 (essentially frozen in time) and to ignore all subsequent amendments, including those found in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). Warner-Chilcott would thereby have FDA, contrary to the statutory language and Congressional intent, impose *multiple* 30-month stays on one narrow class of "old antibiotics" while rejecting this approach for all other pharmaceutical products.

The language of the QI Act and the applicable laws of statutory construction are squarely to the contrary. The Supreme Court and courts at all levels of the federal judiciary have long and

consistently held that, when a later statute (here the QI Act) incorporates or applies an earlier statute (here the Hatch-Waxman Act) by reference, the later statute adopts the earlier statute as it exists at the time of the enactment of the later statute. In other words, the QI Act applies the Hatch-Waxman Act together with all of its amendments in effect as of the date of enactment of the QI Act, regardless of whether the words "as amended" are used or not. The law admits of no controversy on this point, and Warner Chilcott has cited no law that would raise any issues here.

Prior to the enactment of the QI Act, the MMA had already amended the Hatch-Waxman Act to prohibit the application of a 30-month stay to an ANDA that was filed before the listing of a patent in the Orange Book. Here, Actavis' ANDA was on file prior to Warner Chilcott's listing of U.S. Patent No. 6,958,161 ("the '161 patent") in the Orange Book. As such, there should be no 30-month stay associated with Actavis' Paragraph IV certification to the '161 patent and no delay of FDA's review and approval of this ANDA.

BACKGROUND OF THE QI ACT

A. 30-Month Stays Under the Original Hatch-Waxman Act

The 1984 Hatch-Waxman Act amended the Federal Food, Drug and Cosmetics Act ("FDCA") in order to strike a balance between "inducing pioneering research and development of new drugs" and "enabling competitors to bring low-cost, generic copies of those drugs to the market." Teva Pharms., Indus., Ltd. v. FDA, 355 F. Supp. 2d 111, 113 (D.D.C. 2004) (citations omitted). Under its patent listing, certification and litigation provisions, if an ANDA filer submits a Paragraph IV certification, which challenges a listed patent, the ANDA filer must notify the NDA holder and patent owner, providing a detailed statement as to why the relevant patent is not infringed, invalid or unenforceable. 21 U.S.C. § 355(b)(3)(D)(ii). If the patent owner files a patent infringement suit against the ANDA filer within 45 days of receiving the notice letter, FDA may not approve the ANDA for 30 months or until an earlier court decision finding the patent invalid, unenforceable or not infringed. 21 U.S.C. §§ 355(c)(3)(C)(i)–(iv).

The 30-month stay incentivizes the patentee to bring an infringement suit soon after the ANDA is submitted. See Teva Pharms. USA, Inc. v. Novartis Pharms. Corp., 482 F.3d 1330, 1343 n.8 (Fed. Cir. 2007). The 30-month stay was designed to allow the litigation to be resolved *prior to the ANDA being approved*, thus protecting the interests of the NDA holder while at the same time giving the ANDA filer a mechanism to promptly challenge brand patents. See Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30, 40-41 (D.D.C. 2000).

B. FDA Modernization Act of 1997

Antibiotic products were not originally included within the Hatch-Waxman Act but rather were subject to Section 507 of the FDCA. The Food and Drug Administration Modernization

Act of 1997 ("FDAMA"), however, repealed Section 507 of the FDCA and brought certain new antibiotics under the Hatch-Waxman regime. Pub. L. No. 105-115, 111 Stat. 2296 (1997).

Under FDAMA, all antibiotic drug applications did not benefit from the market exclusivity provisions of the Hatch-Waxman Act. Section 125(d)(2) of FDAMA stated that antibiotic drug products that were the subject of an application received by FDA on or before November 20, 1997 (referred to as "old" antibiotics) were not required to be updated with patent information and were not subject to the market exclusivity provisions of Section 505. The purpose of this distinction and FDA's interpretation that Section 125(d)(2)'s exemption applied to all antibiotic moieties that had been previously approved was explained by FDA as follows:

> In interpreting the exclusivity provisions in the Hatch-Waxman Amendments, the agency concluded that Congress did not intend to confer significant periods of exclusivity on minor variations of previously approved chemical compounds. (See, e.g., Congressional Record H9124 (September 6, 1984) (statement of Representative Waxman); H. Rept. 857, Part I, 98th Cong., 2d sess. 38 (1984).) Therefore, the agency determined that it is appropriate to assess whether the drug seeking exclusivity is a new chemical entity, that is, a drug that does not contain any previously approved active moiety. This approach is also consistent with FDA's drug classification system, which assesses and classifies NDA's based upon the characteristics of the active ingredient or ingredients of the product. (See 54 FR 28872 at 28897.) The language of section 125(d)(2) of the Modernization Act likewise supports the conclusion that Congress did not intend to confer exclusivity on, or require patent listing for, products that represent minor or incremental variations on pre-repeal antibiotic drugs.

65 Fed. Reg. 3623, 3625 (Jan. 24, 2000).

C. Medicare Prescription Drug, Improvement, and Modernization Act of 2003

In 2003, the MMA amended the Hatch-Waxman Act, including the provisions applying to 30-month stays. Prior to this time, multiple 30-month stays could arise from "later-listed" patents, that is, those patents submitted to FDA on or after the date the ANDA was filed with FDA. If the ANDA applicant had already filed a Paragraph IV certification on the basis of a patent listed in the Orange Book and was subject to a 30-month stay, a later-listed patent could trigger another lawsuit and another 30-month stay. Using this approach, brand companies could forestall generic competition well beyond the original 30 months.

According to the Federal Trade Commission report that precipitated the MMA changes:

> The history thus far of multiple 30-month stays caused by the filing of later issued patents appears problematic . . . . Multiple 30-month stays prevented FDA approval of the generic applicants' ANDAs for 4 to 40 months beyond the initial

> 30-month period . . . . Even without an additional 30-month stay, later-listed patents still receive the usual protections of patent infringement litigation.

FTC, Generic Drug Entry Prior to Patent Expiration: An FTC Study, at iv-v (July 2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf ("2002 FTC Study").

As a result of its MMA amendments, the Hatch-Waxman Act now provides that a 30-month stay will only be imposed in connection with a patent submitted to FDA by the NDA holder "before the date on which the application [ANDA] (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted." 21 U.S.C. § 355(j)(5)(B)(iii). Senator Kennedy stated:

> *Most significantly, the Hatch-Waxman provisions in this bill* limit brand-name drug companies to only one 30-month stay of approval of generic drugs. This change will stop the multiple, successive 30-month stays that the Federal Trade Commission identified as having delayed approval of generic versions of several blockbuster drugs and cost consumers billions of dollars.

149 Cong. Rec. S 15882, S15884 (Nov. 25, 2003) (emphasis added). See also 149 Cong. Rec. H 12247, H12276 (Nov. 21, 2003) (statement of Rep. Castle).

The MMA amendments to the Hatch-Waxman Act also do not guarantee that any patent owner or NDA holder will necessarily receive a 30-month stay. Senator Schumer stated:

> First, the Gregg-Schumer provisions would limit brand drug companies to a single 30-month stay of generic approval, and only on patents listed at the FDA before a generic application is filed. This way, the 30-month stay *if there is one at all* will run concurrent with FDA approval of the generic application and minimize delay.

149 Cong. Rec. S15670, S15746 (Nov. 24, 2003)(emphasis added).

> FDA also recognizes that there will be situations where 30-month stays are not available:
>
> The MMA does not guarantee that any patent owner or NDA holder will receive a 30-month stay, even if it sues for patent infringement. Rather, the MMA provides the opportunity to obtain a stay only in certain situations . . . . [A] 30-month stay of approval on an ANDA or 505(b)(2) application containing a paragraph IV certification to the patent will ensue if:
>
> - The patent was submitted before the date that the ANDA or 505(b)(2) application (excluding an amendment or supplement) was submitted to FDA, *and*

- The patent owner or NDA holder initiates a patent infringement action on the patent within 45 days of the date that it receives notice of the certification.

No 30-month stay of approval will result from a patent subject to the MMA, even if litigation is initiated based on a paragraph IV certification to the patent, if either of the conditions described above is not satisfied. That is, no 30-month stay of approval will apply if the patent was submitted to FDA *on or after* the date the ANDA or 505(b)(2) application with a paragraph IV certification to the patent was submitted. (Note that this is the case even if the later-submitted patent is the first listed patent to claim the drug described in the ANDA or 505(b)(2) application.)

FDA Guidance for Industry Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Questions and Answers, at 9 (Oct. 2004) (emphasis and parenthetical in original) ("FDA MMA Guidance").

D. QI Act

In enacting the QI Act on October 8, 2008, Congress closed the loophole created by FDAMA and brought all antibiotics under the Hatch-Waxman Act. Among other things, the QI Act provided NDAs covering old antibiotics with three- and five-year marketing exclusivities, where applicable. It also applied provisions of the Hatch-Waxman Act to old antibiotics:

> Notwithstanding section 125, or any other provision, of the Food and Drug Administration Modernization Act of 1997, or any other provision of law, and subject to the limitations in paragraphs (1), (2), (3), the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 [the Hatch-Waxman Act] shall apply to any drug subject to paragraph (1) or any drug with respect to which an election is made under paragraph (2)(A).

QI Act, Section 4(a), 21 U.S.C. § 355(v)(4).

Congress explained the importance of the QI Act as follows:

> The amendment would close a loophole that did away with the incentive to bring old but never approved antibiotics to market. . . . [T]he amendment would make certain molecules that are a part of old active ingredients eligible for recognition as new active ingredients, provided they will be used for a new indication. This provision includes limits that would prevent pharmaceutical manufacturers from abusing the process to extend the life of old active ingredient drugs.

153 Cong. Rec. S5759, 5823 (May 9, 2007) (statement of Sen. Kennedy); see also 154 Cong. Rec. H 10170, 10171 (Sep. 27, 2008) (statement of Rep. Sullivan) ("In addition, this bill provides an important correction in FDA policy regarding the development of antibiotics.").

Finally, the QI Act provides three transitional rules applicable to NDAs containing old antibiotics. These rules: (1) require antibiotic drug NDA sponsors to submit to FDA applicable patents for Orange Book listing within 60 days of enactment; (2) require FDA to list such patents in the Orange Book not later than 90 days after enactment; and (3) create "first applicant" status for 180-day exclusivity purposes for each ANDA applicant that had an ANDA on file prior to the enactment of the QI Act and that submits a Paragraph IV certification to a patent listed under the QI Act not later than 120 days after enactment.

DISCUSSION

According to longstanding and uncontroverted rules of statutory construction, the QI Act must be interpreted to apply the Hatch-Waxman Act as it existed when the QI Act was passed. Warner Chilcott is thus not entitled to a 30-month stay with respect to ANDAs that were filed with FDA prior to the '161 patent being listed in the Orange Book. Warner Chilcott's argument that the reference in the QI Act to the 1984 Hatch-Waxman Act was intended to ignore the Hatch-Waxman provisions that were in effect when the QI Act was adopted is unsupported by the statutory text and legislative history and would lead to absurd results. Moreover, Warner Chilcott's position contradicts the policies underlying the QI and Hatch-Waxman Acts.

A. The QI Act Applies the Hatch-Waxman Act as Amended, Including its Amended 30-Month Stay Provisions

It is black-letter law that, "where one statute incorporates another statute by reference, the statute incorporates the referenced provisions as they exist at the time the incorporating statute is enacted." Ball, Ball and Brosamer, Inc. v. Martin, 800 F. Supp. 967, 972 n.7 (D.D.C. 1992). The federal courts have consistently applied this rule since the earliest years of the American judiciary. The Supreme Court has stated that, when a later statute adopts an earlier statute, the later statute takes the earlier "statute as it exists at the time of adoption." Hassett v. Welch, 303 U.S. 303, 314 (1938) (distinguishing amendments made prior to the enactment of the adopting statute from amendments made after the enactment of the adopting statute). See also Kendall v. United States, 37 U.S. 524, 625 (1838) (same); United States v. New York, New Haven and Hartford R.R. Co., 276 F.2d 525, 540 (2d Cir. 1959) (same); Lawyer's Digest Annotated, Annotation, *Effect of modification or repeal of statutory provision adopted by reference in another provision--federal cases*, 2 L. Ed. 2d 2048 (2008) ("absent proof of a contrary intent on the part of the legislature, the adoption of a statute by reference is an adoption of the law as it existed at the time the adopting statute was passed"); 2B N. Singer & S. Singer, Sutherland Statutory Construction § 51:8 (7th Ed. 2007) (citing cases holding that statutes referencing other

statutes, whether specifically or generally, incorporate their amendments in effect at the time of the enactment of the referencing statute).

Under this well-established rule, the MMA amendments are an integral part of the Hatch-Waxman Act as applied by the QI Act. In fact, many of the original provisions of the 1984 version of the Hatch-Waxman Act, including its 30-month stay provisions, were a legal nullity in October 2008 due to the MMA. As the Supreme Court has explained:

> As a rule of construction, a statute amended is to be understood in the same sense exactly as if it had read from the beginning as it does amended. . . . A statute which is amended is thereafter, and as to all acts subsequently done, to be construed as if the amendment had always been there, and the amendment itself so thoroughly becomes a part of the original statute, that is must be construed, in view of the original statute, as it stands after the amendments are introduced and the matters superseded by the amendments eliminated.

Blair v. Chicago, 201 U.S. 400, 475 (1906). See also Narragansett Indian Tribe v. Nat'l Indian Gaming Comm'n, 158 F.3d 1335, 1339 (D.C. Cir. 1998).

When the QI Act was adopted, the Hatch-Waxman Act provided that a 30-month stay may be imposed where an NDA holder lists a patent in the Orange Book "before the date on which the [ANDA] (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted." 21 U.S.C. § 355(j)(5)(B)(iii). Here, when Warner Chilcott listed the '161 patent in the Orange Book, Actavis' ANDA was already on file with FDA. Thus, no 30-month stay may be imposed.

Warner Chilcott relies entirely on the standard language of the "notwithstanding" clause of Section 4(a) of the QI Act to argue that FDA should ignore the MMA amendments to the Hatch-Waxman Act. As quoted above, this clause provides that the Hatch-Waxman provisions should apply to old antibiotics "notwithstanding section 125, or any other provision, of [FDAMA], or any other provision of law." First, Warner Chilcott argues that the reference to Section 125 and "other provisions of law" means that Congress intended the Hatch-Waxman Act to apply without its subsequent amendments, including the MMA. As demonstrated above, however, a reference to a statute is to be construed as a reference to that statute *as amended* at the time referencing statute is enacted. See Blair, 201 U.S. at 475. If Congress intended to exclude amendments to the Hatch-Waxman Act, such as the MMA amendments, it would have said "notwithstanding any amendment to the Hatch-Waxman Act," but it did not do so.

The correct reading of the "notwithstanding" clause is evident from its actual language. Specifically, this clause made clear that the Hatch-Waxman Act would apply to old antibiotics even though Section 125 of FDAMA stated that the Hatch-Waxman Act would not apply to old antibiotics. To remove all doubt, as is customary in drafting legislation that amends existing law,

Congress also made clear that the Hatch-Waxman Act would apply to old antibiotics despite any other law stating or suggesting that it did not. The only cases cited by Warner Chilcott, in footnote 30 of its Petition, do not construe "notwithstanding" clauses to preclude application of amendments to an adopted statute.

Second, Warner Chilcott argues that Congress demonstrated an intent to disregard the MMA amendments when it referenced the codified subsection of the Hatch-Waxman Act, Section 505(j)(5)(B)(iv), in Section 4(b)(3) but referenced the name of the Hatch-Waxman Act in Section 4(a). Citing a statute by name is, however, a common legislative practice and does not change the rule of statutory construction cited above. See, e.g., New York, New Haven and Hartford R.R., 276 F.2d at 540. Warner Chilcott cites no law to the contrary. In fact, the explanation for these references is simple – in Section 4(a), Congress was referencing the entirety of the Hatch-Waxman Act while in Section 4(b)(3) Congress was referencing a specific subsection of the Hatch-Waxman Act. As any practitioner in this field knows, the use of the general name "Hatch-Waxman Act" is ubiquitous. For example, courts often refer to the Hatch-Waxman Act by its popular name. See, e.g., FTC v. Cephalon, Inc., 551 F. Supp. 2d 21 (D.D.C. 2008). Thus, Warner Chilcott's argument is specious at best.

B. Warner-Chilcott's Interpretation of the QI Act Would Yield Absurd Results that Contravene Legislative Intent

Warner Chilcott's argument also would lead to absurd results and is unsupported by the legislative history. Specifically, Warner Chilcott would have FDA apply one set of rules, based on a Hatch-Waxman Act that is frozen in time, to old antibiotics, and another set of rules to new antibiotics and all other pharmaceutical products. Most jarringly, old antibiotics would be subject to multiple 30-month stays while new antibiotics and all other drug products would not. Warner Chilcott's arguments, therefore, violate the "long-standing rule that a statute should not be construed to produce an absurd result." Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30, 39-40 (D.D.C. 2000) (citing Mova Pharm. Corp. v. Shalala, 140 F.3d 1060 (D.C. Cir. 1998)). See also Nixon v. Mo. Mun. League, 541 U.S. 125, 138 (2004) ("[The] Court will not construe a statute in a manner that leads to absurd or futile results.").

The legislative histories of the QI Act and the MMA also show that Congress intended to abolish multiple stays for all drug products falling under the Hatch-Waxman Act. Senator Kennedy remarked that the QI Act "includes limits that would prevent pharmaceutical manufacturers from abusing the process to extend the life of old active ingredient drugs." 153 Cong. Rec. S5759, 5823 (May 9, 2007). These provisions include, among other things, restricting the 30-month stay from applying where an ANDA is filed before the patent is listed in the Orange Book. In enacting the MMA, he also stated that, "most significantly, the Hatch-Waxman provisions in this bill limit brand-name drug companies to only one 30-month stay of approval of generic drugs." 149 Cong. Rec. S 15882, S15884 (Nov. 25, 2003). Congress would not have abandoned these Hatch-Waxman provisions in the QI Act without expressly saying so.

C. Policy Considerations Also Require Denial of Multiple 30-Month Stays for Old Antibiotics

The QI Act was passed in order to encourage the development of new drug products containing old antibiotic moieties, and provided brand and generic companies with Hatch-Waxman and other incentives to develop such products. Granting a 30-month stay in connection with an NDA that was approved and an ANDA that was submitted *prior to* the enactment of the QI Act does not, however, further this purpose. That is, there is no reason to provide the 30-month stay incentive to a brand company to file an NDA if that company has already filed an NDA. Moreover, applying a 30-month stay to ANDAs that have been on file for quite some time before a patent is listed in the Orange Book would undermine the Hatch-Waxman Act's central purpose to "get generic drugs into the hands of patients at reasonable prices – fast." In re Barr Labs., Inc., 930 F.2d 72, 76 (D.C. Cir. 1991). In effect, Warner Chilcott's argument would penalize these ANDA filers by not starting the 30-month clock until long after the ANDA has been filed, and by subjecting these filers to the risk of multiple 30-month stays.

Warner Chilcott's policy arguments on pages 11-13 of its Petition are without merit. Specifically, Warner Chilcott argues that a construction of the QI Act that precludes a 30-month stay with respect to ANDAs on file before a patent is listed "would render FDCA section 505(v)(4) as added by the QI Act effectively meaningless for old antibiotics with pending ANDAs . . . ." (Petition at 11.) While no 30-month stay would be available, there are numerous provisions of the Hatch-Waxman Act that would be applicable under new Section 505(v)(4) in such an instance. For example, Warner Chilcott was able to list the '161 patent in the Orange Book and has consequently received notice of Paragraph IV certifications from five separate ANDA filers. As a result, Warner Chilcott has initiated patent infringement suits against these ANDA filers. Prior to the QI Act, Warner Chilcott would have been forced to wait until the ANDA filers received final approval before filing suit. Thus, the QI Act has significantly benefited Warner Chilcott with respect to pending ANDAs.

In addition, Warner Chilcott argues that a denial of a 30-month stay here "would also essentially penalize [Warner Chilcott] for listing the patent 'late,' even though the only reason for that 'late' listing was the lack of any statutory basis to list patents for old antibiotics before enactment of the QI Act." (Petition at 12.) The 30-month stay, however, was never an absolute right given to brand companies. When the Hatch-Waxman Act was amended by the MMA in 2003, Congress and FDA both recognized that 30-month stays would not always be available. For example, a patent holder will not obtain a 30-month stay for a patent that issued after an ANDA has been filed, even if the patent holder did nothing to delay the issuance of the patent. Senator Schumer stated that "the 30-month stay *if there is one at all* will run concurrent with FDA approval of the generic application and minimize delay." 149 Cong. Rec. S 15670, S15746 (Nov. 24, 2003) (emphasis added). FDA has also recognized that:

> [N]o 30-month stay of approval will apply if the patent was submitted to FDA *on or after* the date the ANDA or 505(b)(2) application with a paragraph IV certification to the patent was submitted. (Note that this is the case even if the later-submitted patent is the first listed patent to claim the drug described in the ANDA or 505(b)(2) application.)

FDA MMA Guidance, at 9 (Oct. 2004) (emphasis and parenthetical in original).

CONCLUSION

Under black-letter rules of statutory construction, the plain language of the QI Act applied the Hatch-Waxman Act as it existed when the QI Act was passed. Warner Chilcott's arguments to the contrary border on the frivolous and are belied by the legislative history and by policy considerations. Accordingly, FDA should not delay its review and approval of pending ANDAs, and should deny Warner Chilcott's Petition.

CERTIFICATION

I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to the party on whose behalf I have submitted this petition on or about the following dates: the date that the QI Act was enacted (October 8, 2008); the date the '161 patent appeared in the public version of the Orange Book (December 2008); and shortly after Warner Chilcott's citizen petition became publicly available (January 29, 2009). If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: Axinn, Veltrop & Harkrider LLP expects to receive from Actavis Elizabeth LLC in the ordinary course of business at our standard rates for our legal services rendered. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this response.

Sincerely,

Chad Landmon /TKH

Chad A. Landmon

cc: Gary J. Buehler
Elizabeth Dickinson, Esq.
David Read, Esq.
Lisa Graver, Esq.
James D. Veltrop, Esq.